

OFFICE OF ATTORNEY GENERAL LAWRENCE G. WASDEN

AVERAGE WHOLESALE PRICE LITIGATION REPORT AUGUST 2013

Introduction

In 2007, Attorney General Wasden filed lawsuits against 33 pharmaceutical companies for publishing false and inflated "Average Wholesale Prices" (AWPs) for their pharmaceutical drugs. Idaho Medicaid used these AWPs in determining reimbursement to pharmacies for pharmaceutical drugs dispensed to Medicaid patients. Idaho alleged that the false and inflated AWPs resulted in Idaho Medicaid paying too much for such drugs. On July 10, 2013, the District Court for the Fourth Judicial District in the State of Idaho, Ada County, approved a settlement between the State of Idaho and Novartis Pharmaceuticals Corporation. This settlement concluded six years of "average wholesale price litigation" in which the Attorney General recovered more than \$28 million for the State of Idaho.

Background

Idaho Medicaid is a program that is jointly funded by the state and federal governments. It provides health care coverage for certain individuals with low income, including children, pregnant women, older adults, and people with disabilities. This health care coverage includes prescription drugs, which are dispensed without charge to Medicaid patients. Idaho Medicaid then reimburses the pharmacy or other dispenser for the cost of the drugs plus a dispensing fee.

Idaho's lawsuit alleged that, for many years, pharmaceutical companies published, or caused to be published, an AWP for their drugs. The AWP was disseminated to the public through publication in medical compendia. The publishers of the medical compendia relied on the prices reported to them by the pharmaceutical manufacturers. Until recently, Idaho Medicaid based its pharmaceutical reimbursement formula on the published AWP. In most instances, Idaho Medicaid reimbursed pharmacies for prescription drugs based on a formula that included AWP plus a dispensing fee. Idaho alleged that a false and inflated AWP resulted in Idaho taxpayers, through the Idaho Medicaid program, paying more for pharmaceutical products than they should have paid.

Investigation

The Attorney General became aware that many pharmaceutical manufacturers misrepresented the true AWP for their drugs. His Consumer Protection Division reviewed volumes of documents and data, analyzed AWP lawsuits brought by the United States Department of Justice and other state attorneys general, met with the administrators of the Idaho Department of Health and Welfare and its Division of Medicaid, and studied Idaho's pharmaceutical reimbursements. The Attorney General determined that:

- 1. False and inflated AWPs were disseminated in Idaho;
- 2. Such conduct violated the Idaho Consumer Protection Act;
- Idaho Medicaid utilized these false and inflated AWPs in reimbursing pharmacists for the costs of prescription drugs; and
- 4. Accordingly, the State lost millions of dollars as a result of such conduct.

Due to the scope of the litigation, the Attorney General engaged the assistance of outside counsel with experience litigating state AWP claims, Miner, Barnhill & Galland, P.C. ("Miner

Barnhill"). The firm also represented Alaska, Hawaii, Illinois, Kentucky, South Carolina, and Wisconsin in AWP litigation, allowing more efficient use of resources. With Miner Barnhill's assistance, the Attorney General compared AWPs, as reported by the various pharmaceutical companies, to sales data obtained from pharmaceutical wholesalers. The review identified which companies and for which drugs false and inflated AWPs were published. The Attorney General found that, for these manufacturers, the difference between the actual wholesale price of a drug and published AWPs for the same drugs ranged from 25% to more than 2,000%.

The Attorney General wrote to approximately 40 pharmaceutical companies, expressing his concerns regarding possible violations of the Idaho Consumer Protection Act. The Act prohibits unfair or deceptive acts or practices in trade and commerce and declares it unlawful to state or imply that goods are being offered at wholesale prices, or use a term of similar meaning, unless the prices are at or below the current prices that most retailers customarily pay when they buy such goods for resale. In other words, if a company states that a price is wholesale, that price must be a true wholesale price or lower.

Prior to litigation, the Attorney General invited each manufacturer to meet with him to discuss his concerns. Every potential defendant was offered an opportunity to meet with the Attorney General prior to litigation. Certain companies chose to meet with the Attorney General, others did not. Some provided information during the meetings that resulted in the Attorney General's closure of his investigation of those companies. Others met with the Attorney General and agreed to resolve the office's concerns without the need for litigation. Several companies met with the Attorney General and entered into tolling agreements that allowed additional time for negotiations prior to litigation. And, other companies met without reaching a resolution.

Litigation

The Attorney General ultimately filed suit in Fourth District Court in Ada County on January 26, 2007. The Attorney General alleged violations of the Idaho Consumer Protection Act, as a result of the defendant pharmaceutical companies publishing false and inflated AWPs. The suit was filed against the following defendants:

- Abbott Laboratories
- Alpharma USPD Inc.
- AstraZeneca Pharmaceuticals LP
- AstraZeneca LP
- Barr Laboratories, Inc.
- Centocor, Inc.
- Ivax Corp.
- Ivax Pharmaceuticals, Inc.
- Janssen Pharmaceutical Products, LP
- Johnson & Johnson
- McNeil-PPC, Inc.
- Merck & Co., Inc.
- Ortho Biotech Products, LP
- Ortho-McNeil Pharmaceutical, Inc.
- Par Pharmaceutical Cos.
- Purepac Pharmaceutical Co.
- Sandoz, Inc., formerly known as Geneva Pharmaceuticals, Inc.
- Teva Pharmaceuticals USA, Inc.
- Watson Pharma, Inc., formerly known as Schein Pharmaceuticals, Inc.
- Watson Pharmaceuticals, Inc.

On June 8, 2007, the Attorney General filed suit in Fourth District Court in Ada County against the following additional defendant pharmaceutical companies:

- Aventis Pharmaceuticals Inc.
- Ben Venue Laboratories, Inc.
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Forest Laboratories, Inc.
- Mylan Laboratories, Inc.
- Mylan Pharmaceuticals, Inc.
- Novartis Pharmaceuticals Corp.
- Pfizer Inc.
- Pharmacia Corp.
- Roxane, Inc., now known as Boehringer Ingelheim Roxane, Inc.
- Schering-Plough Corp.
- SmithKline Beecham Corp., doing business as GlaxoSmithKline
- Warrick Pharmaceuticals Corp.

The Attorney General requested damages on behalf of the State and injunctive relief for the alleged misrepresentations of the AWPs of the defendants' drugs.

The complaints were met with motions to dismiss filed by all of the defendants. The matters were briefed and hearings were held. The defendants set forth many arguments as to why the cases should be dismissed. The Court denied the motions to dismiss and allowed the cases to proceed. The Court, however, limited the State's recovery to the damages incurred by Idaho Medicaid during the four years before the State filed its lawsuits, plus any time allowed under the individual tolling agreements.

The matters continued to the discovery phase. The State produced to defendants approximately 250,000 pages of documents and multiple sets of data. The defendants produced millions of pages of documents to the State. Depositions of current and former Idaho Medicaid employees were held in Boise, and depositions of current and former employees of the defendants were held throughout the country.

Numerous motions were briefed and argued before the Court. Expert witnesses were hired by both sides to calculate and analyze damages and to provide information on the pharmaceutical industry. The cases were prepared for trial, requiring thousands of hours of work by the Attorney General's office and outside counsel. Ultimately, all of the defendants settled before the trials began. Two groups of defendants, however, settled just days before their respective trials were set to begin.

Settlements

Idaho Medicaid ceased using AWP as a Medicaid reimbursement formula pursuant to a law passed in 2011. However, data from companies may still be an important part of reimbursement for prescription drugs, and thus the settlements require the defendants to provide certain confidential data to the State. In addition, the defendants paid money to the State. The settlements total more than \$28 million.

DATE	COMPANY	SETTLEMENT
07/12/05	TAP Pharmaceutical Products, Inc. (Lupron drug only)*	\$252,027.44
10/29/06	Dey, Inc. and Dey, L.P.*	\$1,180,600.00
06/25/08	Bristol-Myers Squibb Company and Apothecon, Inc.*	\$1,738,719.00
07/23/09	Ben Venue Laboratories, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Roxane, Inc.	\$660,000.00
06/10/10	Alpharma USPD Inc. and Purepac Pharmaceutical Co.	\$1,274,623.00
08/23/10	Teva Pharmaceuticals USA, Inc., Ivax Corp., Ivax Pharmaceuticals, Inc., and Barr Laboratories, Inc.	\$1,900,000.00
10/22/10	Sandoz, Inc.	\$1,650,000.00
01/14/11	Warrick Pharmaceuticals Corporation and Schering-Plough Corp.	\$750,000.00
03/31/11	Par Pharmaceuticals Cos., Inc.	\$1,700,000.00
08/10/11	AstraZeneca Pharmaceuticals LP and AstraZeneca LP	\$2,500,000.00
09/28/11	Merck Sharp & Dohme Corp. , f/k/a Merck & Co., Inc.	\$1,600,000.00
12/05/11	Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutical Products, LP, McNeil-PPC, Inc., Ortho Biotech Products, LP, Ortho-McNeil Pharmaceutical, Inc.	\$2,000,000.00
01/27/12	Mylan Inc. and Mylan Pharmaceuticals Inc.	\$625,000.00
04/13/12	SmithKline Beecham Corp., d/b/a GlaxoSmithKline	\$2,600,000.00
06/01/12	Forest Laboratories, Inc.	\$790,000.00
07/12/12	Watson Pharma, Inc. and Watson Pharmaceuticals, Inc.	\$1,700,000.00
07/31/12	Aventis Pharmaceuticals Inc.	\$828,500.00
12/27/12	Pfizer Inc. and Pharmacia Corp.	\$2,900,000.00
02/05/13	Abbott Laboratories	\$1,000,000.00
07/10/13	Novartis Pharmaceuticals Corp.	\$750,000.00
	TOTAL:	\$28,399,469.44

^{*} Pre-Litigation Settlement

The majority of the settlement funds, \$24,112,037.59, reimbursed the State, in part, for the extra money it paid for prescription drugs based on false and inflated AWPs.

Because Idaho Medicaid receives approximately 70% of its funding from the federal government, federal law requires that the federal government receive its share of any recoveries of Medicaid funding. Therefore, \$13,557,797.54 was "returned" to the federal government for its share of the settlements, in the form of credits for future payments to Idaho Medicaid. \$7,161,357.03 was the State of Idaho's share of the settlements, and was placed into the General Fund for appropriation by the Legislature. The General Fund is the pool of money the Legislature uses to fund the State's share of Idaho Medicaid, as well as other programs.

From the settlement proceeds, the Attorney General's office was reimbursed \$896,587 in attorney fees and \$24,885.35 in costs. Idaho Medicaid was reimbursed \$8,000 for its expenses. Miner Barnhill was paid \$2,684,143.65 in attorney fees and reimbursed \$681,815.85 for costs of litigation (such as expert witness fees, travel, etc.).

Conclusion

The AWP litigation was important to the State of Idaho for several reasons. First and foremost, the litigation helped reimburse moneys spent by the taxpayers of the State caused by the alleged violations and will help to ensure that such conduct does not occur again. Second, it sent a message to the pharmaceutical industry that violations of the Idaho Consumer Protection Act are not tolerated by the State. Third, it demonstrates that the Attorney General is prepared to litigate against the most powerful companies in the world.